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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,135	02/06/2004	Lukas Eisermann	PC806.00/31132.121	8402
46333 7590 02/05/2008 HAYNES AND BOONE, LLP 901 Main Street Suite 3100 Dallas, TX 75202			EXAMINER COMSTOCK, DAVID C	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 02/05/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/774,135

Applicant(s)

EISERMANN ET AL.

Examiner

David Comstock

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12 and 31-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13-30 and 37-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) .
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 13-30 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marnay (WO 01/01893; cited by Applicant).

Marnay discloses the claimed invention including components 2, 3/4, flanges, e.g. 17, convex projection 25, concave recess 12 and the offset relationship (see, e.g., Figs. 1-3, 6 and 7, elements 25 and 12 appear to be offset in at least an anterior-posterior direction). The components have a notch, e.g., 22, 23. The flanges comprise sharp portions, e.g., 7 and shearing edges of leading end. The flanges have through holes, e.g., 21. Marnay discloses the claimed invention except, perhaps, for unambiguously showing or disclosing that the articulation features (i.e. the convex projection and concave recess) are or could be offset. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have located the articulation features at any location or distance or range of distances from an edge or edges of the device, since it has been held that mere relocation of parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70. Moreover, it has been held that where the general conditions of a claim are disclosed in

the prior art (e.g. an articulating disc prosthesis having articulation features located some distance from an edge), discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. It is also noted that Marnay may not explicitly describe a bone growth promoting material on the device or forming the device of a cobalt-chrome-molybdenum metallic alloy. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the device with a bone growth promoting material to enhance fixation of the device to bone and to have formed the device of a cobalt-chrome-molybdenum metallic alloy for durability, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

Applicant's arguments filed 02 January 2008 have been fully considered but they are not persuasive.

It is noted that even if there may be ambiguity or disagreement about whether the articulation features of the device of Marnay et al. are offset in a certain direction (which, it is noted, depends on one's perspective as well as the intended implantation direction, i.e., the offset configuration is not defined in the claims in necessarily absolute terms), it would have been obvious to a person of ordinary skill in the art to have located the articulation features at any desired location or distance or range of distances from any edge or edges of the device, as set forth above in the rejection. Moreover, it is noted

that a person of ordinary skill in the art, i.e. a surgeon or medical device engineer, would easily recognize that modifying the location of articulation features would change the characteristics of the device to address at least the need of satisfying varying requirements of patients having differing spinal anatomies sizes, conditions, deformities, etc. It is axiomatic that every patient is unique and requires personalized treatment. Given this basic fact and that many common deformities and conditions of the spine involve offset vertebrae that would require an appropriate and complementary treatment, it cannot be reasonably believed that a person of ordinary skill in the art would not have considered an offset configuration for a patient having a condition that would manifestly call for the same.

Conclusion

The finality of the last Office action is withdrawn as being premature.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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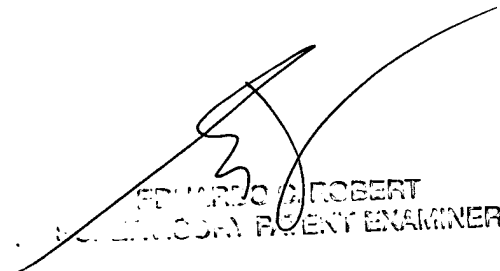
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. Please leave a detailed voice message if examiner is unavailable. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. Comstock



EDUARDO ROBERT
PATENT EXAMINER